

MARKED VERSION OF AMENDMENTS TO THE CLAIMS

In the Claims:

1. (Amended) A thermal adhesion granulation process for preparing direct tableting formulations or aids, comprising the step of subjecting all or part of a mixture comprising:

(a) from about 5 to about 99 % by weight of one or more diluent excipients and/or from 0 to about 99% by weight of a pharmaceutically-active ingredient;

(b) from about 1 to about 95 % by weight of a binder excipient; and optionally with,

(c) from 0 to about 10% by weight of a disintegrant excipient;

to heating at a temperature range of from about 30 to about 130°C under the condition of ~~from about 0.1 to about 20% initial moisture content and/or from about 0.1 to about 20% initial~~ content of a pharmaceutically-acceptable organic solvent in a closed system [under] with mixing by tumble rotation until [the formation of] granules form.

13. (Amended) A process as defined in claim 12, wherein [the microcrystalline cellulose is of a type in which] about 90% of the microcrystalline cellulose particles are in the particle size range from about 1 µm to about 125 µm, and the average particle size is from about 10 µm to about 70 µm.

18. (Amended) A process as defined in claim 1, wherein the binder excipient further contains from 0 to about 10% [()by weight with respect to the binder()] of an anticaking agent.

19. (Amended) A process as defined in claim 18, wherein the binder excipient contains from about 0.01 to about 10% [()by weight with respect to the binder()] of an anticaking agent.

20. (Amended) A process as defined in claim 18, wherein the binder excipient contains from about 2 to about 4% [(by weight with respect to the binder)] of an anticaking agent.

22. (Amended) A product of [thermal adhesion granulation] the process of claim 1 [for preparing direct tableting formulations or aids as defined in claim 1].

23. (Amended) A powder mixture of soluble polyvinyl pyrrolidone containing from about 0.01 to about 10% [(by weight with respect to the polyvinyl pyrrolidone)] of dibasic calcium phosphate anhydrous.